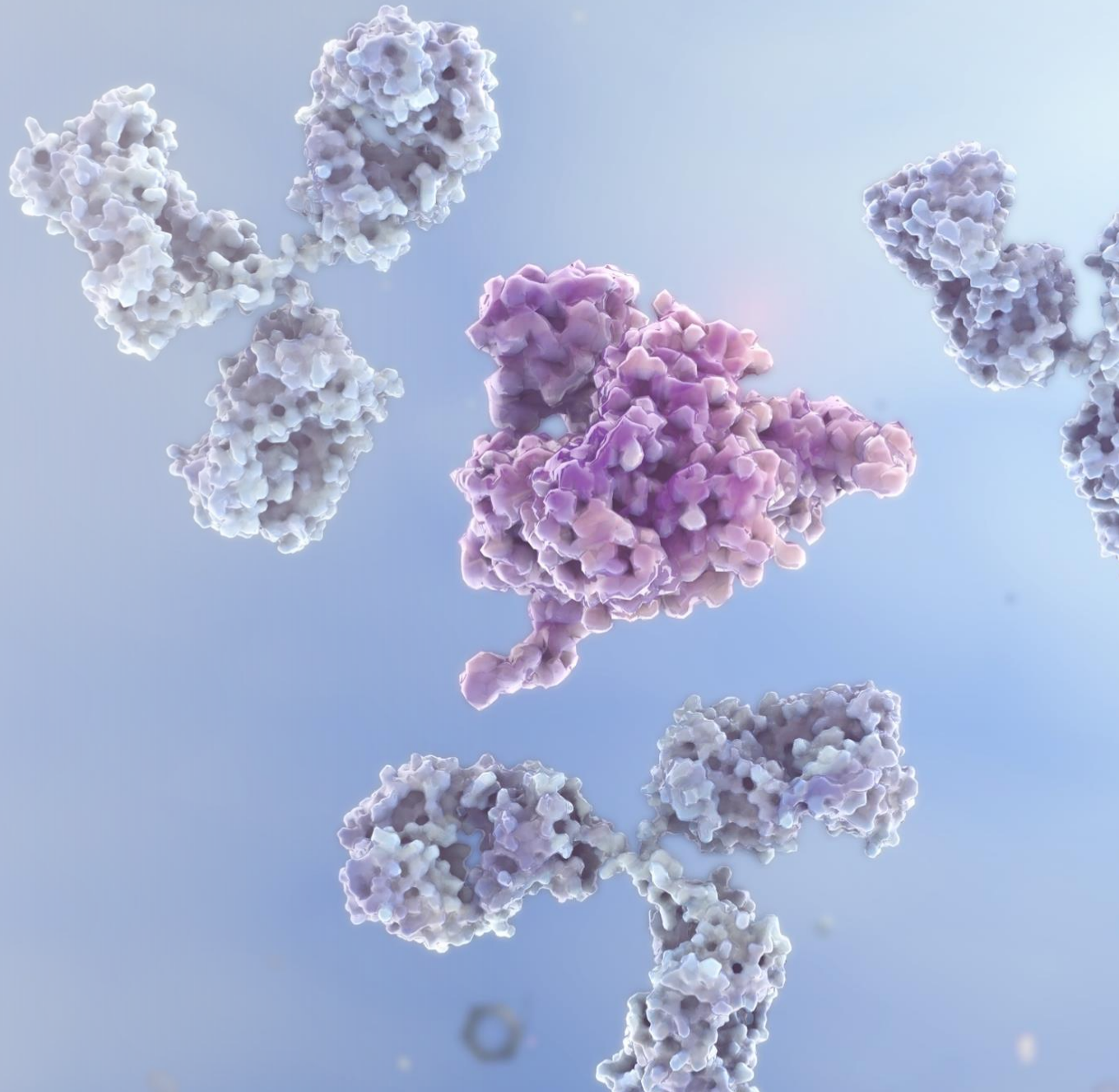


Interim Report

January – March 2025



Hansa delivers solid Q1 2025 IDEFIRIX® sales performance; completed enrolment in Phase 3 Post Authorization Efficacy and Safety (PAES) study in kidney transplantation; announced Renée Aguiar-Lucander as new CEO

Business Update

- > **Solid Q1 IDEFIRIX sales performance.** Q1 2025 product sales of IDEFIRIX totaled 65.7 MSEK representing an 39% increase over prior year (47.4 MSEK). Revenue for Q1 2025 totaled 66.3 MSEK representing an 18% increase over the prior year (56.0 MSEK).
- > **IDEFIRIX achieves additional pricing and reimbursement.** In Q1, Hansa secured reimbursement for IDEFIRIX in Austria, Estonia, and Portugal as a desensitization treatment for adult kidney transplant patients with a positive crossmatch against an available deceased donor organ. Currently, IDEFIRIX has pricing and reimbursement in more than 75% of the European kidney transplant market and secured market access in 18 markets across Europe.
- > **Post Authorization Efficacy and Safety (PAES) Phase 3 study enrolment completed.** In January 2025, the Company announced the completion of the PAES study enrolment. The study is part of the Company's obligation under the European conditional marketing authorization by the European Medicines Agency (EMA). The study remains on track to read out in 2026 and is intended to support full marketing authorization in Europe. With the study enrolment complete, the Company expects to see an increase in new and repeat utilization in key centers across Europe that participated in the study and now have clinically experience and protocols in place to treat highly sensitized kidney transplant patients

Clinical Pipeline Update

- > **U.S. ConfIdes trial (kidney transplantation):** The Company remains on track to deliver a data read out in second half 2025 for the 20-HMedIdeS-17 study (ConfIdes), a pivotal Phase 3 trial evaluating imlifidase as a potential desensitization therapy compared to treatment according to standard of care (SoC) to enable kidney transplantation in highly sensitized patients. Randomization was completed in May 2024 and submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) is expected in second half 2025 following data readout.
- > **15-HMedIdeS-09 in Guillain Barré Syndrome (GBS):** Following positive data from the 15-HMedIdeS-09 Phase 2 trial and indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS), the data has been accepted for oral presentation at an upcoming medical conference in 2025. The trial and indirect treatment comparison demonstrated imlifidase's potential to address significant unmet need in GBS.
- > **GNT-018-IDES in Crigler Najjar (Gene Therapy):** In collaboration with Genethon, the Company continues to progress GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome with pre-existing antibodies against adeno-associated virus (AAV) vectors. The trial will evaluate the efficacy and safety of a single intravenous administration of Genethon's gene therapy GNT-0003 following pre-treatment with imlifidase in patients with severe Crigler-Najjar syndrome and pre-formed antibodies to AAV serotype 8 (AAV8).
- > **HNSA-5487 positive regulatory agency interaction:** The Company had a positive meeting with the German Federal Institute for Drugs and Medical Devices (BfArM) confirming the proposed clinical trial design in myasthenia gravis (MG).
- > **SRP-9001-104 in Duchenne Muscular Dystrophy (Sarepta):** Several patients have been enrolled in Sarepta Therapeutic's Phase 1b trial evaluating the use of imlifidase as a pre-treatment in its Duchenne Muscular Dystrophy gene therapy program. Recruitment and dosing are temporarily halted in several ELEVDIS studies following a safety update in March. An independent data monitoring committee concurred that the overall risk-benefit profile remains favorable and there should be no material impact to timelines.

Subsequent Events

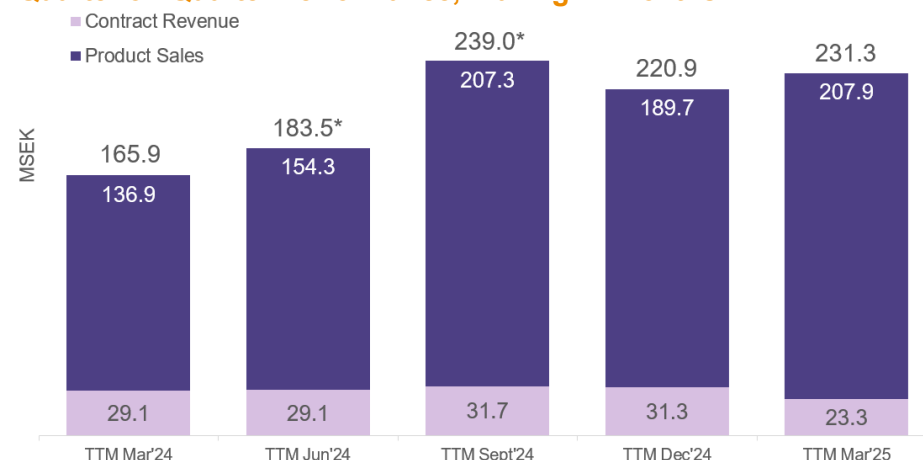
- > **The Company announced Renée Aguiar-Lucander as Chief Executive Officer:** Aguiar-Lucander has been appointed CEO effective immediately. Søren Tulstrup will be stepping down from his position by mutual agreement as CEO after seven years of dedicated service to the Company.

Financial Summary

MSEK, unless otherwise stated – unaudited	Q1 2025	Q1 2024	FY 2024
Total Revenue	66.3	56.0	220.9
-thereof: Product sales	65.7	47.4	189.7
Provision ¹	-	-	(49.6)
Net revenue after provision	66.3	56.0	171.3
SG&A expenses	(76.0)	(91.3)	(344.3)
R&D expenses	(64.3)	(103.0)	(375.7)
Loss from operations	(93.4)	(159.4)	(637.9)
Loss for the period	(37.1)	(218.6)	(807.2)
Net cash used in operations	(151.9)	(189.1)	(674.9)
Cash and short-term investments	250.2	541.5	405.3
EPS before and after dilution (SEK)	(0.55)	(4.15)	(12.85)
Number of outstanding shares	67,814,241	52,671,796	67,814,241
Weighted average number of shares before and after dilution	67,814,241	52,671,796	62,834,848
No of employees at the end of the period	138	166	135

¹ Actual product sales for the full year 2024 totaled 189.7 MSEK. Sales were offset by a provision totaling 49.6 MSEK associated with volume discounts and rebates. Including the provision, 2024 product sales totaled 140.1 MSEK.

Quarter on Quarter Performance, Trailing 12 Months*



* Sales in Q2-2024 and Q3-2024 were offset by a provision totaling 49.6 MSEK. The provision was associated with volume discounts and rebates. Including the provision taken in 2024 product sales totaled 140.1 MSEK.



“This quarter the Company delivered strong growth with total revenue of 66.3 MSEK and products sales of 65.7 MSEK. This represents an overall increase in product sales revenue of 39% as compared to previous year. While quarterly product sales continue to fluctuate due to the unpredictable nature of the organ allocation system, we remain confident in our ability to deliver significant year-over-year growth. In Q1, the Company completed enrolment in the Post Authorization Efficacy and Safety (PAES) study, continued to secure access and reimbursement in key European markets, and is seeing growing repeat utilization of IDEFIRIX in transplant centers across Europe. We also continue to progress key pipeline catalysts with several important data readouts planned for the second half of 2025.”

Peter Nicklin
Chairman of the Board, Hansa Biopharma

In Q1 2025, the Company delivered strong sales performance for IDEFIRIX, with product sales totalling 65.7 MSEK representing a 39% increase over prior year (Q1 2024: 47.4 MSEK). While the organ allocation market remains unpredictable and directly impacts our quarterly sales, we remain confident in our ability to significantly increase revenue year on year.

During this quarter, we saw continued successful implementation of pricing and reimbursement agreements across Europe, including cascading national level agreements down to regional level in key markets as well as achieving new national level agreements in several countries. Additionally, growing repeat utilization in key centers following a successful first transplant combined with the addition of new-to-IDEFIRIX centers is helping to drive adoption of IDEFIRIX as a new standard of care in desensitization of highly sensitized kidney transplant patients. Further, growth was underscored by the clinical community’s adoption of international guidelines and consensus on the use of IDEFIRIX in kidney transplantation for the desensitization of highly sensitized patients.

Early in the quarter, *Transplant International* published an international consensus on the appropriate use of imlifidase in the management of highly sensitized kidney transplant patients, supporting the development and integration of center-specific guidelines.

In January, the Company announced completion of enrolment in the Post Authorization Efficacy and Safety (PAES) Phase 3 study. As part of our obligation under the EMA conditional marketing authorization, this study is intended to support full marketing authorization in Europe. The study is on track for a data read out in 2026 and now that enrolment is complete, we expect to see more use of commercial IDEFIRIX in key centers across Europe that participated in the study.

The Company is also making good progress with both the U.S. ConfldeS Phase 3 study in kidney transplantation and the GOOD-IDES-02 Phase 3 study in anti-GBM.

Both studies are on track for read out in the second half of 2025. In addition, following the Q4 2024 announcement of positive results from the 15-HMedIdeS-09 Phase 2 study in Guillain-Barré Syndrome (GBS) and indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS), we are on track to present the data at an upcoming global medical conference and publication in a peer reviewed journal in 2025.

In line with our commitment to enable gene therapies for a broader range of patients with anti-AAV antibodies, our collaborations with leading gene therapy companies continue to progress. In Q4 2024, we announced the initiation of GNT-018-IDES, a Phase 2 trial in Crigler Najjar to evaluate the efficacy and safety of Genethon’s gene therapy, GNT-0003 following pre-treatment with imlifidase, and patient enrolment is now ongoing.

The Phase 1b trial SRP-9001-104 with Sarepta Therapeutics (Sarepta) is evaluating the use of imlifidase as a pre-treatment to Sarepta ELEVIDYS (delandistrogene moxeparvovec) gene therapy in Duchenne Muscular Dystrophy (DMD). Following a safety update in March for ELEVIDYS, several clinical studies, including SRP-9001-104, were temporarily halted. An independent data monitoring committee concurred that the overall risk-benefit profile remains favorable. This information will be submitted at the request of EU regulators. There should be no material impact to timelines. ELEVIDYS is FDA approved as a one-time treatment in individuals with DMD with a confirmed mutation in the DMD gene who are at least four years old.

The development of the Company’s next generation molecule for repeat dosing, HNSA-5487, remains on track. We recently had very positive interaction with BfArM confirming the clinical development plan for HNSA-5487 in myasthenia gravis (MG). This follows the positive results the Company shared in Q4 2024 from a 12-month analysis of NICE-01, the first in-human trial of HNSA-5487, which demonstrated that the molecule can very robustly and rapidly reduce IgG levels, has clear redosing potential, and a favorable safety and tolerability profile in the study subjects.

Earlier today, the Company announced Renée Aguiar-Lucander has been appointed Chief Executive Officer effective immediately. Søren Tulstrup will be stepping down from his position by mutual agreement as CEO after seven years of dedicated service to the Company.

Imlifidase: Commercial, Clinical and Regulatory Update

Commercial Update

EU: Kidney transplantation in highly sensitized patients

The launch of IDEFIRIX continues to progress and the Company delivered strong commercial performance in Q1 2025. To date, the Company has secured access and reimbursement in 18 countries across Europe. In January, IDEFIRIX received reimbursement in Austria, Estonia, and Portugal. IDEFIRIX was granted conditional approval by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch antibodies against an available deceased donor in August 2020.

The Company continues to see a growing body of data, real-world evidence and published consensus on the utilization of imlifidase as a desensitization strategy for highly sensitized kidney transplant patients.

In January 2025 *Transplant International* published an international consensus on the appropriate use of imlifidase in the management of highly sensitized kidney transplant patients and supports the development and integration of center-specific guidelines.² Additional publications on the use of imlifidase in desensitization include a paper published by the European Society of Organ Transplantation (ESOT) (2024) and real-world evidence published in *Kidney International Reports* (June 2024) demonstrating acceptable short-term efficacy and safety profile of imlifidase in highly sensitized kidney transplant. The data was also presented at the American Society of Transplantation's annual congress in 2024.

Most recently in January 2025, the Spanish Guide to Kidney Transplantation in Highly Sensitized Patients with anti-HLA antibody was published and provides recommendations for the management of renal transplantation in highly sensitized patients with donor-specific anti-HLA antibodies.³ Finally, 153 patients eligible for IDEFIRIX were identified by transplant centers in countries participating in Eurotransplant's Desensitization Program. Eurotransplant is an international allocation system responsible for the allocation of donor organs across eight countries.

Pipeline Update

Post Authorization Efficacy and Safety Study (PAES) - 20-HMedIdeS-19

Enrolment for the trial was completed in January 2025 (50 out of 50 targeted) and the Company is on track for data readout in the second half of 2026. This study is part of the Company's obligation under the European conditional marketing authorization following conditional approval. The study will be used to further investigate long-term graft survival in 50 highly sensitized kidney transplant patients treated with IDEFIRIX and is expected to support full marketing authorization. There were 22 centers participating in the trial with 14 enrolling patients. This underscores the continued interest of the clinical community in

gaining experience with IDEFIRIX. Following the completed enrolment, these centers now have clinical experience and protocols in place to treat highly sensitized kidney transplant patients.

ConfideS U.S. Phase 3 Trial - 20-HMedIdeS-17

As previously reported, randomization of the 20-HMedIdeS-17 study (ConfideS), the Company's pivotal Phase 3 trial, was completed in May 2024. The trial is evaluating imlifidase as a potential desensitization therapy compared to treatment according to standard of care (SoC) to enable kidney transplantation in highly sensitized patients. The Company remains on track for a data read out and submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in second half 2025.

Long-term follow-up Trial of Kidney Transplant Patients - 17-HMedIdeS-14

In February 2025, the 17-HMedIdeS-14 trial data was published in *Transplantation Direct* demonstrating that DSA rebound is common, but antibody strength lessens in the long term and longitudinally persisting DSAs did not lead to premature graft failure. This data was also accepted for oral presentation at an upcoming medical congress.⁴

In 2024, pooled five-year data including data from the 17-HMedIdeS-14 study was published in *American Journal of Transplantation*.⁵ This data was also presented at the American Society of Transplantation's annual congress and SITO in June and October, respectively.

17-HMedIdeS-14 trial data pooled with data from four Phase 2 trials showed sustained positive outcomes out to five years in most highly sensitized patients who received an imlifidase-enabled kidney transplant. Patient survival was 90 percent (death censored) and graft survival was 82 percent and in line with SoC outcomes seen at three years post-transplant. The five-year extended pooled analysis is a continuation of the analysis at three years of crossmatch positive only patients.

The 17-HMedIdeS-14 trial is a prospective, observational, long-term follow-up study of patients treated with imlifidase prior to kidney transplantation to measure long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration.

Global Phase 3 anti-glomerular basement membrane (Anti-GBM) Disease Trial - GOOD-IDES-02

The GOOD-IDES-02 Phase 3 trial is enrolled (50 of 50 patients). The data readout remains on track for the second half of 2025. The trial is an open label, controlled, randomized, multi-center trial evaluating renal function in patients with severe anti-GBM disease using imlifidase plus SoC versus SoC only.

1. Kamar, Nassim et al. Imlifidase in Highly Sensitized Kidney Transplant Recipients With a Positive Crossmatch Against a Deceased Donor. *Kidney International Reports*, Volume 9, Issue 10, 2927 – 2936
2. Furian, Lucrezia & Heemann, Uwe & Bengtsson, Mats & Bestard, Oriol & Binet, Isabelle & Böhmig, Georg & Boletis, John & Briggs, David & Claas, Frans & Couzi, Lionel & Cozzi, Emanuele & Crespo, Marta & de Vries, Aiko & Diekmann, Fritz & Durlik, Magdalena & Glotz, Denis & Helantera, Ilkka & Jackson, Annette & Jordan, Stanley & Naesens, Maarten. (2025). Desensitization With Imlifidase for HLA-Incompatible Deceased Donor Kidney Transplantation: A Delphi International Expert Consensus. *Transplant International*. 37. 10.3389/ti.2024.13886
3. <https://www.ont.es/wp-content/uploads/2024/12/Guia-tx-renal-pacientes-altamente-sensibilizados-con-DSA.pdf>
4. Jaffe, Ian S. BS1,2; Runström, Anna MSc3; Tatapudi, Vasishta S. MD2,4; Weldon, Elaina P. MSN, ACNP-BC1,2; Deterville, Cecilia L. MS1,2; Dieter, Rebecca A. PharmD1,2; Montgomery, Robert A. MD, DPh11,2; Lonze, Bonnie E. MD, PhD1,2; Mangiola, Massimo PhD2,5. Clinical Outcomes and Donor-specific Antibody Rebound 5 y After Kidney Transplant Enabled by Imlifidase Desensitization. *Transplantation Direct* 11(2):p e1752, February 2025. | DOI: 10.1097/TXD.0000000000001752
5. Jordan, Stanley C. Maldonado, Angela Q. Lonze, Bonnie E. Sjöholm, Kristoffer Lagergren, Anna Montgomery, Robert A. Runström, Anna Desai, Niraj M. Legendre, Christophe Lundgren, Torbjörn von Zur Mühlen, Bengt Vo, Ashley A. Tollema, Jan Lefèvre, Paola Lorant, Tomas et al. Long-term outcomes at 5 years posttransplant in imlifidase-desensitized kidney transplant patients. *American Journal of Transplantation*, Volume 0, Issue 0

Phase 2 Guillain-Barré Syndrome (GBS) Study - 15-HMedldeS-09

The Company announced positive full results from the 15-HMedldeS-09 single arm Phase 2 study of imlifidase in GBS and an indirect treatment comparison of the 15-HMedldeS-09 study data to the International Guillain-Barré Syndrome Outcome Study (IGOS), a worldwide prospective study by the Inflammatory Neuropathy Consortium on prognosis and biomarkers of GBS. Presentation of the data at an upcoming medical congress and publication in a peer-reviewed journal are planned for the second half of 2025.

Genethon Phase 2 Trial in Crigler Najjar – GNT-018-IDES

In December 2024, Genethon and Hansa announced initiation of GNT-018-IDES, a Phase 2 trial in patients with Crigler-Najjar syndrome with pre-existing antibodies against adeno-associated virus (AAV) vectors. The trial is evaluating the efficacy and safety of a single intravenous administration of Genethon's gene therapy GNT-0003 following pre-treatment with imlifidase in patients with severe Crigler-Najjar syndrome and pre-formed antibodies to AAV serotype 8 (AAV8). The Companies are on track to deliver data in the second half of 2025.

Sarepta Phase 1b Trial in Duchenne Muscular Dystrophy (DMD) – SRP-9001-104

The SRP-9001-104 Phase 1b trial is evaluating the use of imlifidase as a pre-treatment to Sarepta Therapeutic's (Sarepta) ELEVIDYS (delandistrogene moxeparvovec) gene therapy in Duchenne Muscular Dystrophy (DMD). Following a safety update in March for ELEVIDYS, several clinical studies, including SRP-9001-104, were temporarily halted at the request of EU reference member country authorities.

An independent data monitoring committee concurred that the overall risk-benefit profile remains favorable to continue dosing in the paused studies with without changes to study protocols. This information will be submitted at the request of EU regulators. No material impact on timelines for the study is anticipated. ELEVIDYS is FDA approved as a one-time treatment in individuals with DMD with a confirmed mutation in the DMD gene who are at least four years old.

Preclinical Update

AskBio - pre-treatment ahead of gene therapy in Pompe disease

AskBio and Hansa announced a collaboration agreement in January 2022 to evaluate the use of imlifidase as a pre-treatment for AskBio's gene therapy in Pompe disease. In May 2024, AskBio presented pre-clinical data as part of the Hansa-AskBio partnership at the American Society of Gene and Cell Therapy's (ASGCT) annual meeting. The data demonstrated that imlifidase can help keep AAVs in circulation for a longer time increasing the window for gene therapy transduction.

For further information regarding AskBio's programs please visit www.askbio.com

HNSA-5487: Clinical and Regulatory Update

HNSA-5487 Phase 1 Trial – NICE-01

Recently the company had a positive regulatory interaction with the German Federal Institute for Drugs and Medical Devices (BfArM) aligning on the proposed clinical trial design for HNSA-5487 in myasthenia gravis (MG).

Results of a 12-month follow up analysis from the NICE-01 trial of HNSA-5487, the Company's next generation IgG-cleaving molecule, were announced on October 7, 2024. The analysis assessed IgG recovery, immunogenicity and the potential for redosing HNSA-5487 in chronic autoimmune diseases.

High-level results from the NICE-01 trial demonstrated that HNSA-5487 was safe and well tolerated among study subjects, with rapid depletion of IgG observed with increasing doses in all healthy study subjects. Pharmacokinetics (PK) and pharmacodynamics (PD) were in line with expectations. The trial included a total of 36 healthy male and female adult participants. The Company will focus initial clinical development activities in chronic autoimmune diseases where IgG plays a role in disease pathology with recurring attacks.

Broad clinical pipeline



	Preclinical	Phase 1	Phase 2	Phase 3	Marketing authorization	Marketed	Partner	Status	Next anticipated milestone
Imlifidase									
EU: Kidney transplantation in highly sensitized patients ^{1,2}	[Progress bar]			[Progress bar]	[Progress bar]			Commercialization ongoing ● Post approval Clinical Phase 3 ongoing	EU: Additional agreements around reimbursement / Post authorization study data read out in 2H 2026
U.S. "ConfIdeS": Kidney transplantation in highly sensitized patients ^{1,2}	[Progress bar]			[Progress bar]				Clinical Phase 3 ongoing	Data readout in 2H 2025
GOOD-IDES-02: Anti-GBM antibody disease	[Progress bar]			[Progress bar]				Clinical Phase 3 ongoing	Data readout in 2025
16-HMedIdeS-12: Active Antibody Mediated Rejection (AMR)	[Progress bar]			[Progress bar]				Clinical Phase 2 completed	
15-HMedIdeS-09: Guillain-Barré Syndrome (GBS)	[Progress bar]			[Progress bar]				Clinical Phase 2 completed	Publication in peer-reviewed journal Preparation of Phase 3 trial
Investigator-initiated trial in ANCA-associated vasculitis ³	[Progress bar]			[Progress bar]				Clinical Phase 2 ongoing	Complete enrollment (10 patients)
SRP-9001-104: Pre-treatment ahead of gene therapy in Duchenne Muscular Dystrophy (DMD)	[Progress bar]			[Progress bar]				Clinical Phase 1b ongoing	Complete enrollment
Pre-treatment ahead of gene therapy in Limb-Girdle Muscular Dystrophy (LGMD)	[Progress bar]			[Progress bar]				Preclinical research ongoing	Preclinical research
Pre-treatment ahead of gene therapy in Pompe disease	[Progress bar]			[Progress bar]				Preclinical research ongoing	Preclinical research
GNT-018-IDES: Pre-treatment ahead of gene therapy in Crigler-Najjar syndrome	[Progress bar]			[Progress bar]				Clinical Phase 2 ongoing	Complete enrollment
HNSA-5487									
NICE-01: HNSA-5487 – Lead candidate from the NiceR program	[Progress bar]			[Progress bar]				Clinical Phase 1 completed	Alignment with regulatory authorities on clinical development pathway in neuro-autoimmune diseases

¹ Results from the Phase 1 study have been published, Winstedt et al. (2015) PLOS ONE 10(7)

² Lorant et al., American Journal of Transplantation and 03+04 studies (Jordan et al., New England Journal of Medicine)

³ Investigator-initiated study by Dr. Adrian Schreiber and Dr. Philipp Enghard, at Charité Universitätsmedizin, Berlin, Germany

Financial Review 2025: January-March

Revenue

Revenue for the first quarter 2025 totaled 66.3 MSEK (Q1 2024: 56.0 MSEK) consisting of IDEFIRIX product sales of 65.7 MSEK (Q1 2024: 47.4 MSEK) and contract revenue of 0.6 MSEK (Q1 2024: 8.5 MSEK) related to revenue from the agreement with Axis-Shield.

Sales General & Administrative (SG&A) expenses

SG&A expenses for the first quarter 2025 totaled 76.0 MSEK (Q1 2024: 91.3 MSEK). The result from the restructuring activities during 2024 is now showing and has reduced total SG&A expenses compared to the same period previous year. Non-cash expenses for the Company's long-term incentive programs (LTIP) were included in SG&A costs and totaled 1.9 MSEK for the first quarter 2025 (Q1 2024: 8.9 MSEK).

Research & Development (R&D) expenses

R&D expenses for the first quarter of 2025 totaled 64.3 MSEK (Q1 2024: 103.0 MSEK). Compared to 2024, the decrease in expense was primarily driven by savings associated with restructuring activities offset by the ongoing U.S. Phase 3 ConfldeS study, EMA post-approval commitments, the ongoing anti-GBM Phase 3 clinical study and CMC development expense for HNSA-5487. Non-cash expenses for the Company's LTIP program were included in R&D expense and totaled 2.0 MSEK for the first quarter 2025 (Q1 2024: 4.1 MSEK).

Other operating income/expenses, net and finance income/expenses, net

Other operating income/expenses, net, primarily included gains or losses from foreign exchange rate fluctuations in operations. In the first quarter 2025, the Company recorded income of 1.0 MSEK, compared to 3.0 MSEK in expense in the first quarter of 2024. The change is primarily due to a strengthening in the exchange rate of the Swedish Krona versus primarily US dollar and EUR, affecting deferred revenue as well as accounts payable and receivable positions on the balance sheet.

Financial income/expenses, net, for the first quarter of 2025, totaled 56.7 MSEK of income (Q1 2024 expense of 29.6 MSEK). The financial expenses for the first quarter developed positively due to the strengthening of the Swedish Krona compared to the US dollar and the accrued interest for the loan. The first quarter 2025, financial expenses included in non-cash interest expense associated with the NovaQuest loan amounted to 35.9 MSEK (Q1 2024: 31.2 MSEK), favourable foreign exchange fluctuations associated with the NovaQuest loan to 95.5 MSEK (Q1 2024 unfavourable: 51.0 MSEK), and other items (see Note 4).

Financial results

The loss from operations for the first quarter 2025 totaled 93.4 MSEK (Q1 2024: 159.4 MSEK). The decrease in Hansa's operating loss compared to the prior period was driven by increased sales as well as lower overall expenses.

The first quarter loss totaled 37.1 MSEK (Q1 2024: 218.6 MSEK).

Cash flow, cash and investments

Net cash used in operating activities for the first quarter 2025 totaled 109.7 MSEK (Q1 2024: 136.7 MSEK). The change compared to the prior year was driven by higher sales and lower operating expenses and a positive impact associated with changes in working capital.

Cash and cash equivalents totaled 250.2 MSEK at December 31, 2024, compared to 405.3 MSEK at December 31, 2024.

Parent Company

The parent company's revenue for the first quarter of 2025 totaled 66.3 MSEK (Q1 2024: 56.0 MSEK). During the first quarter 2025 the parent company loss totaled 68.3 MSEK (Q1 2024: 247.1 MSEK). The parent company shareholders' equity at March 31, 2025 totaled 610.8 MSEK compared to 674.4 MSEK at December 31, 2024.

The Group consists of the parent company, Hansa Biopharma AB, and the subsidiaries Cartela R&D AB, Hansa Biopharma Ltd, Hansa Biopharma Inc., Hansa Biopharma Italy S.r.l. and Hansa Biopharma Australia PTY LTD. On March 31, 2025, Hansa Biopharma Inc. had thirteen employees, Hansa Biopharma Ltd seven employees and Hansa Biopharma S.r.l. three employees.

Long-term incentive programs

At Hansa Biopharma's previous Annual General Meetings, shareholders resolved to adopt various share-based LTIP programs. As of March 31, 2025, the Company incurred non-cash equity-based compensation expense under the following LTIP programs: 2020, 2021, 2022, 2023 and 2024.

The respective non-cash costs related to the ongoing LTIP programs are summarized in the table below. For further information on the different LTIP programs, please refer to Hansa Biopharma's 2024 Annual Report which can be found at www.hansabiopharma.com.

Ongoing programs	LTIP 2020	LTIP 2021	LTIP 2022	LTIP 2023	LTIP 2024
Maximum number of issuable shares*	633,776	325,000	819,904	1,025,358	1,724,470
Number of allocated outstanding share rights and options	487,520	250,000	630,695	797,944	1,342,000
Estimated total cost including social contributions for outstanding share rights and options, KSEK	25,863	15,474	42,667	16,092	40,223
Total cost per program, including social contributions as of March 31, 2025 YTD, KSEK	-345	-16	1,626	817	1,826
Total costs, including social contributions, as of March 31, 2025 YTD, KSEK					3,908

Risks and uncertainties

Hansa's business is influenced by a number of factors, the effects of which on the Company's earnings and financial position in certain respects cannot be controlled by the Company at all, or in part. In an assessment of the Company's future development, it is important, alongside the possibilities for growth in earnings, to consider these risks.

Since Q4 2022 Hansa has capitalized development costs related to IDEFIRIX in connection with the conditional approval the Company received from the EMA (see Note 5). Based on the conditional approval from the EMA, the parent company of the group also revalued the underlying intangible asset related to IDEFIRIX in 2023 (see Note 6). Both the assessment to start capitalizing development costs and the write up of the intangible assets in the parent company was based on the assessment that Hansa will eventually receive a final approval from EMA for the sale of IDEFIRIX. The current conditional approval from EMA requires Hansa to conduct two clinical trials to secure a final approval:

- a five-year follow-up clinical study on previously performed Phase II studies of treatment in 46 patients. This concerns a follow-up on patients that have been treated with IDEFIRIX. This clinical study was finalized and submitted to EMA in December 2023. In 2024 EMA finalized its review and the study was approved.
- a post-authorization efficacy and safety (PAES) study, of 50 transplanted patients treated with IDEFIRIX with a reference group of 50 transplant patients not treated with IDEFIRIX which is the standard treatment for kidney transplants. After finalizing the treatment, the patients will be monitored for one year to analyze the long-term effect of the drug. The objective is to see if the treatment of highly sensitized patients with IDEFIRIX are as successful as the standard treatment. Hansa currently has no indication that the study would be unsuccessful.

Based on the fact that the follow-up study is already approved and that there are no current indications that the PAES study would be unsuccessful, Hansa considers the risk of not being able to fulfill EMA's conditions for final approval to be remote.

Risk factors include, among others, uncertainties with regard to clinical trials and regulatory approvals, collaboration and partnerships, intellectual property issues, dependence on key products, market and competition, manufacturing, purchasing and pricing, as well as dependence on key persons and financial risks.

The Board of Directors and management remain focused on cash flow and work continuously to ensure long-term and sustainable financing of current and planned development projects. Given current priorities and project, the Company anticipates a cash runway into Q4 2025. Further expense management would allow the Company to extend its cash runway into early 2026. There are a number of possible alternatives to secure the financing for the Company and the Board and management will continue to evaluate financing opportunities. The Company continues to explore opportunities to fund operations, including debt restructuring and a range of business development opportunities, such as regional and global development and commercialization partnerships, the outcome of which naturally cannot be predicted at this time. Risks and uncertainties which are considered to have greatest significance for Hansa Biopharma are described in more detail in the English version of the Company's 2024 Annual Report (pages 32-35).

On a regular basis, Hansa's Board of Directors and senior management review the development of these risks and uncertainties. No material changes from the presentation in the 2024 Annual Report have been identified as of the date of this quarterly report.

Financial Review 2025: January-March (continued)

Other information

Contacts

Evan Ballantyne, Chief Financial Officer
Hansa Biopharma
E-mail: ir@hansabiopharma.com

Stephanie Kenney, VP Global Corporate Affairs
Hansa Biopharma
E-mail: media@hansabiopharma.com

Legal disclaimer

This financial report includes statements that are forward-looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are developments within research programs. This is a translated version of the Swedish original.

Dividend

The board proposes that no dividend will be paid for the financial year 2024.

Financial calendar 2024/2025

To be determined	Annual General Meeting
July 17, 2025	Half-year Report for January – June 2025
October 23, 2025	Interim Report for January – September 2025

Shareholder information

Brief facts

Listing	Nasdaq OMX Stockholm
Number of shares March 31, 2025	67,814,241
Market Cap March 31, 2025	~1.49 BSEK (USD ~\$152 M)
Ticker	HNSA
ISIN	SE0002148817

Top 10 Shareholders as of March 31, 2025

Shareholder Name	Number of Shares	Ownership %
Redmile Group LLC	13,156,700	19.40%
Braidwell LP	8,247,600	12.16%
Theodor Jeansson Jr.	2,620,000	3.86%
Hansa Biopharma AB	2,204,667	3.25%
Nexttobe AB	2,155,379	3.18%
Fourth Swedish National Pension Fund (AP4)	2,094,000	3.09%
Thomas Olausson	1,917,000	2.83%
Handelsbanken Fonder	1,847,989	2.73%
Sphera Funds Management	1,107,000	1.63%
Avanza Pension	1,098,270	1.62%
All other	31,365,636	46.25%
Total Shares Outstanding	67,814,241	100.00%

Source: Modular Finance compiled and processed data from various sources, including Euroclear, Morningstar, FactSet and the Swedish Financial Supervisory Authority (Finansinspektionen).

Hansa Biopharma had approximately 20,000 shareholders as of March 31, 2025.

Assurance

The Board of Directors and the Chief Executive Officer affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the group's financial position and results. The interim report has been prepared in accordance with generally accepted accounting principles for the group and the parent company and gives a fair overview of the development of the group's and the parent company's operations, financial positions, and results. This report has not been reviewed by the company's auditors.

Lund, Sweden, April 23, 2025

Peter Nicklin
Chairman of the Board

Hilary Malone
Board member

Eva Nilsagård
Board member

Mats Blom
Board member

Florian Reinaud
Board member

Anders Gersel Pedersen
Board member

Jonas Wikström
Board member

Unaudited Condensed Financial Statements

Unaudited condensed consolidated statement of financial position

KSEK	No	March 31		Dec 31
		2025	2024	2024
ASSETS				
Non-current assets				
Intangible assets	5	213,579	147,502	197,333
Property and equipment		4,247	6,003	4,682
Right-of-use assets		11,946	18,839	13,198
Total non-current assets		229,772	172,344	215,213
Current assets				
Inventories		2,890	1,201	2,610
Trade receivables & unbilled revenues		183,568	72,596	144,965
Current receivables, non-interest bearing		38,822	42,944	32,574
Cash and cash equivalents		250,200	541,465	405,280
Total current assets		475,480	658,206	585,429
TOTAL ASSETS		705,252	830,550	800,642
EQUITY AND LIABILITIES				
Shareholders' equity				
		(623,744)	(374,209)	(589,833)
Non-current liabilities				
Long-term loan	4	1,005,074	927,116	1,064,645
Deferred tax liabilities		146	375	168
Provisions		3,347	5,899	4,259
Lease liabilities		5,093	12,466	6,678
Refund liabilities		55,761	-	59,038
Contingent consideration	3	-	909	-
Total non-current liabilities		1,069,421	946,765	1,134,778
Current liabilities				
Tax liabilities		2,197	1,534	2,705
Lease liabilities		7,967	7,540	7,684
Current liabilities, non-interest bearing		61,861	62,662	55,491
Deferred revenue		14,898	36,458	16,334
Refund liabilities		83,827	52,851	64,484
Accrued expenses		88,825	96,949	108,989
Total current liabilities		259,575	257,994	255,687
TOTAL EQUITY AND LIABILITIES		705,252	830,550	800,642

Unaudited condensed consolidated statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q1		12 Months
		2025	2024	2024
Revenue	2	66,349	55,981	171,316
Cost of revenue		(20,530)	(18,158)	(83,554)
Sales, general and administration expenses		(75,992)	(91,250)	(344,270)
Research and development expenses	5	(64,264)	(102,965)	(375,716)
Other operating income/(expenses), net		1,021	(2,999)	(5,654)
Loss from operations		(93,416)	(159,391)	(637,878)
Financial income		86,164	5,236	20,834
Financial expenses	4	(29,486)	(64,363)	(187,165)
Loss before tax		(36,738)	(218,518)	(804,209)
Tax		(337)	(61)	(3,034)
Loss for the period		(37,075)	(218,579)	(807,243)
Loss for the period attributable to owners of the parent		(37,075)	(218,579)	(807,243)
Loss per share, basic and diluted (SEK)		(0.55)	(4.15)	(12.85)
Other comprehensive income/(loss)				
Items that have been, or may be reclassified to profit or loss for the period:				
Translation differences		(1,573)	771	1,350
Other comprehensive income/(loss) for the period		(1,573)	771	1,350
Total comprehensive loss		(38,648)	(217,808)	(805,893)

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy that enables desensitization for highly sensitized kidney transplant patients. Our drug discovery and development pipeline is based on the Company's proprietary IgG-cleaving enzyme technology platform. We are focused in four strategic therapeutic areas – transplantation, autoimmune diseases, gene therapy and new therapies – where there are little to no treatment options available. Hansa is based in Lund, Sweden with operations in Europe and the U.S. Find out more at www.hansabiopharma.com.

Unaudited condensed consolidated statement of changes in shareholders' equity

KSEK	January-March		December
	2025	2024	2024
Opening balance of shareholders' equity	(589,833)	(167,876)	(167,876)
Result for the period	(37,075)	(218,579)	(807,243)
Translation reserve	(1,573)	771	1,350
Net comprehensive loss	(38,648)	(217,808)	(805,893)
Transactions with the group's owner			
Proceeds from new share issuance, net ¹	-	-	354,308
Long term incentive programs	4,737	11,475	29,629
Total transactions with the group's owner	4,737	11,475	383,937
Closing balance of shareholders' equity	(623,744)	(374,209)	(589,833)

¹ Total share issue cost amounted to SEK 17,845 KSEK.

Unaudited condensed consolidated statement of cash flow

KSEK	Q1		12 Months
	2025	2024	2024
Cash Flows from Operating Activities			
Loss for the period	(37,075)	(218,579)	(807,243)
Adjustment for non-cash items ¹	(72,015)	81,613	180,890
Interest received and paid, net	79	455	19,107
Income taxes paid	(714)	(146)	(3,611)
Cash flow from operations before change in working capital	(109,725)	(136,657)	(610,857)
Changes in working capital	(42,148)	(52,486)	(64,027)
Net cash used in operating activities	(151,873)	(189,143)	(674,884)
Investing activities			
Acquisition of property and equipment	(628)	(116)	(116)
Cash flow from investing activities	(628)	(116)	(116)
Financing activities			
Proceeds from new share issue, net of transaction cost ²	-	-	354,308
Payment of lease liabilities	(1,302)	(1,859)	(7,503)
Cash flow from financing activities	(1,302)	(1,859)	346,805
Net change in cash	(153,803)	(191,118)	(328,195)
Cash and cash equivalents at beginning of period	405,280	732,060	732,060
Currency exchange variance, cash and cash equivalents	(1,277)	523	1,415
Cash and cash equivalents, end of period	250,200	541,465	405,280

¹ Values are mainly costs of share-based incentive programs including social contributions and depreciation, partly offset by certain capitalized development costs (see further in Note 5).

² Total share issue cost amounted to SEK 17,845 KSEK.

Parent Company – Unaudited condensed statement of financial position

KSEK	Note	March 31		12 Months
		2025	2024	2024
ASSETS				
Non-current assets				
Intangible assets	5,6	1,433,309	1,486,124	1,446,684
Property and equipment		4,247	6,003	4,682
Right-of-use assets		11,946	18,839	13,198
Investment in subsidiaries		34,186	31,754	34,194
Total non-current assets		1,483,688	1,542,720	1,498,758
Current assets				
Inventories		2,890	1,201	2,610
Trade receivables & unbilled revenues		183,568	72,596	144,965
Current receivables, non-interest bearing		37,877	42,504	31,160
Cash and cash equivalents		235,192	537,441	385,103
Total current assets		459,527	653,742	563,838
TOTAL ASSETS		1,943,215	2,196,462	2,062,596
EQUITY AND LIABILITIES				
Shareholders' equity	6	610,814	981,304	674,449
Non-current liabilities				
Long-term loan	4	1,005,074	927,116	1,064,645
Provisions		3,347	5,899	4,259
Lease liabilities		5,093	12,466	6,678
Refund liabilities		55,761	-	59,038
Contingent consideration	3	-	909	-
Total non-current liabilities		1,069,275	946,390	1,134,620
Current liabilities				
Tax liabilities		476	1,334	1,119
Lease liabilities		7,967	7,540	7,684
Liabilities, group companies		11,859	17,360	11,480
Current liabilities, non-interest bearing		61,638	60,411	55,448
Deferred revenue		14,898	36,458	16,334
Refund liabilities		83,827	52,851	64,484
Accrued expenses		82,461	92,814	96,978
Total current liabilities		263,126	268,768	253,527
TOTAL EQUITY AND LIABILITIES		1,943,215	2,196,462	2,062,596

Parent Company – Unaudited condensed statement of profit or loss and other comprehensive income (loss)

KSEK	Note	Q1		12 Months
		2025	2024	2024
Revenue	2	66,349	55,981	171,316
Cost of revenue		(50,322)	(47,949)	(202,721)
Sales, general and administration expenses		(78,028)	(89,713)	(346,455)
Research and development expenses	5	(63,693)	(103,255)	(375,351)
Other operating income/(expenses), net		718	(2,988)	(6,242)
Loss from operations		(124,976)	(187,924)	(759,453)
Financial income		86,164	5,236	20,848
Financial expenses	4	(29,484)	(64,364)	(187,164)
Loss before tax		(68,296)	(247,052)	(925,769)
Income tax	6	(71)	(71)	(607)
Loss for the period		(68,367)	(247,123)	(926,376)
Other comprehensive loss for the period		-	-	-
Total comprehensive loss for the period		(68,367)	(247,123)	(926,376)

Parent Company – Unaudited condensed statement of changes in shareholders' equity

KSEK	March 31		12 Months
	2025	2024	2024
Opening balance of shareholders' equity	674,449	1,216,945	1,216,945
Result for the period	(68,367)	(247,123)	(926,376)
Other comprehensive income/(loss) for the period	-	-	-
Net comprehensive loss	(68,367)	(247,123)	(926,376)
IP write-up, net			-
Proceeds from new share issuance, net ¹	-	-	354,308
Long term incentive programs	4,732	11,482	29,572
Total other transactions	4,732	11,482	383,880
Closing balance of shareholders' equity	610,814	981,304	674,449

¹ Total share issue cost amounted to SEK 17,845 KSEK.

Financial Notes

Note 1 Basis of preparation and accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting, and recommendation RFR2 of the Swedish Reporting Board, Accounting for Legal entities. The same accounting principles have been used as in the latest annual report except for what is stated below. Hansa's Annual Report for 2024 was published on March 21, 2025, and is available at www.hansabiopharma.com. Disclosures in accordance with IAS 34.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Revenue

Income per significant category of income KSEK	Q1		Full year
	2025	2024	2024
Group			
Revenue			
Product sales ¹	65,678	47,448	140,111
Contract revenue, Axis-Shield agreement	671	651	2,605
Cost reimbursement, Axis-Shield agreement	-	501	640
Contract revenue, Sarepta, AskBio agreement	-	7,381	27,960
	66,349	55,981	171,316
Parent Company			
Revenue			
Product sales ¹	65,678	47,448	140,111
Contract revenue, Axis-Shield agreement	671	661	2,605
Cost reimbursement, Axis-Shield agreement	-	501	640
Contract revenue, Sarepta, AskBio agreement	-	7,381	27,960
	66,349	55,981	171,316

¹ Actual product sales for the full year 2024 totaled 189.7 MSEK. Sales were offset by a provision totaling 49.6 MSEK associated with volume discounts and rebates. Net of the provision, 2024 product sales totaled 140.1 MSEK.

Note 3 Fair value of financial instruments

The Group measures its investments in interest funds and its financial liability for contingent consideration at fair value. The fair value of the financial liability for contingent consideration at March 31, 2025 totaled 0.0 MSEK (Q1, 2024: 0.9 MSEK) and belongs to Level 3 in the fair value hierarchy. The Group does not currently hold any interest funds. All other financial instruments are measured at amortized cost. The carrying values of those instruments are considered reasonable approximations of their fair values.

Note 4 Long-term loan

On July 18, 2022, the Company entered into a US \$70.0 million funding agreement with NovaQuest. The funding was accounted for as a liability and classified as debt because the Company has an unavoidable obligation to settle the agreement in cash. The debt will be accounted for over the life of the funding agreement.

The net proceeds from the funding agreement totaled US \$69.2 million after the deduction of transaction costs. The transaction costs were capitalized and offset against the carrying value of the debt and are being amortized over the term of the debt.

Under the terms of the funding agreement, the Company was required to make quarterly mid-single-digit royalty payments to NovaQuest on future worldwide annual net sales of imlifidase, commencing upon approval by the U.S. FDA of imlifidase in kidney transplantation or anti-GBM. In addition, Hansa will make certain milestone payments to NovaQuest upon FDA approval of imlifidase in kidney transplantation or anti-GBM disease. The agreement also provides for time-based catch-up payments if specified payment amounts have not been received by NovaQuest by specified dates. Under the agreement, repayments must begin no later than January 31, 2026, regardless of whether the aforementioned approvals were achieved, with the final potential catch-up payment due on January 31, 2029. The company is obligated to repay a total of US \$140.0 million in the form of milestones, royalty payments and/or catch-up payments.

Hansa has also entered into a security agreement under which the Company has pledged and provided a broad security interest to NovaQuest in, and to, certain assets, proceeds and IP rights related to imlifidase in kidney transplantation in highly sensitized patients and anti-GBM disease.

The Company records the difference between the principal and the total payments as interest expense over the term of the debt by applying the effective-interest-rate method. Based on the progress of the payments, the Company will recalculate the effective interest each reporting period until the debt obligation has been satisfied.

On March 31, 2025, the loan totaled 1,005.1 MSEK, including 328.4 MSEK in accrued interest.

Note 5 Intangible assets – Internally-generated intangible assets

Expenditures related to research activities are recognized as expense in the period in which it is incurred. An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized only if all the following criteria have been demonstrated in accordance with IAS 38:

- *the technical feasibility of completing the intangible asset so that it will be available for use or sale;*
- *the intention to complete the intangible asset and use or sell it;*
- *the ability to use or sell the intangible asset;*
- *how the intangible asset will generate probable future economic benefits;*
- *the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and*
- *the ability to measure reliably the expenditure attributable to the intangible asset during its development.*

The amount initially recognized for internally-generated intangible assets is the sum of the expenditures incurred from the date when the intangible asset first meets all the recognition criteria listed above. Development expenses, for which no internally-generated intangible asset can be identified, are expensed in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

Financial Notes continued

The Company determined that IDEFIRIX and its conditional approval by EMA to enable kidney transplantation in highly sensitized patients met all the above criteria as of Q4 2022.

As of March 31, 2025, the total capitalized development expenses related to fulfilling the IDEFIRIX EMA post-approval commitments amount to 213.6 MSEK, with 16.2 MSEK capitalized during 2025. These capitalized development costs are subject to regular amortization over their useful life, which is projected to extend until the end of 2032. Total accumulated amortization at March 31, 2025 was 28.5 MSEK.

Note 6 Intangible assets – Recognition of write-up

As of June 30, 2023, Hansa recognized a write-up of 1,430.0 MSEK in intangible assets in the statutory financial statements of the parent company Hansa Biopharma AB, in accordance with Chapter 4, Section 6 of the Swedish Annual Accounts Act (1995:1554) and RFR 2.

The write-up relates to IDEFIRIX, which has received a conditional market authorization in the European Union (EU)/EEA and United Kingdom for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Following the write-up, the asset will have a gross value of 1,500.0 MSEK in Hansa Biopharma AB's financial statements.

The write-up increased the restricted shareholder equity in Hansa Biopharma AB by 1,430.0 MSEK. It also created a taxable temporary difference, leading to the recognition of a deferred tax liability of 294.6 MSEK, which decrease restricted shareholder equity. As a result of recognizing the deferred tax liability, Hansa recognized a deferred tax asset of 294.6 MSEK in its profit or loss statement, increasing unrestricted shareholder equity, related to previously unrecognized tax losses.

The intangible asset will be subject to regular amortization over its estimated useful life of 12 years.

As of March 31, 2025, the Company recorded accumulated amortization of 224.2 MSEK in its statutory financial statements, thereby reducing the previously recorded intangible asset by the same amount. As a result, the Company has recorded an adjustment of 46.2 MSEK to its previously recorded deferred tax assets and tax liabilities due to amortization.

The write-up and subsequent amortization of the intangible asset does not impact the consolidated IFRS financial statements of the Hansa Group.

Glossary

Adeno-associated virus (AAV)

AAV is a versatile viral vector technology that can be engineered for very specific functionality in gene therapy applications.

Allogeneic hematopoietic stem cell transplantation (HSCT)

Allogeneic HSCT, also known as "bone-marrow" transplantation, involves transferring the stem cells from a healthy person (the donor) to the patient's body after high-intensity chemotherapy or radiation. The donated stem cells can come from either a related or an unrelated donor.

AMR

Antibody mediated transplant rejection.

Antibody

One type of protein produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM.

Anti-GBM disease (Goodpasture syndrome)

Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease

Diseases that occur when the body's immune system reacts against the body's own structures.

Biologics License Application (BLA)

A Biologics License Application (BLA) is submitted to the Food and Drug Administration (FDA) to obtain permission for distribution of a biologic product across the United States.

CD20

B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

Clinical studies

Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical phase 1

The first time a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical phase 2

Refers to the first time a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical phase 3

Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

DSA

Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

EMA

The European Medicines Agency (EMA) is an EU agency for the evaluation of medicinal products.

Enzyme

A protein that accelerates or starts a chemical reaction without itself being consumed.

ESOT

The European Society for Organ Transplantation (ESOT) is an umbrella organisation which overlooks how transplantations are structured and streamlined.

FDA or US FDA

U.S. Food and Drug Administration.

Guillain-Barré syndrome

Guillain-Barré syndrome (GBS), is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBP

Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HLA

Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IgG

IgG, Immunoglobulin G, is the predominant type of antibody in serum.

Imlifidase

Imlifidase, is the immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies while leaving other Ig-isotypes intact.

IND

Investigational New Drug (IND) application is required to get approval from the FDA to administer an investigational drug or biological product to humans.

INN

International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substance or active pharmaceutical ingredient.

In vitro

Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo

Term within biomedical science to indicate that experiments or observations are made in living organisms.

IVD

IVD, In vitro diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Marketing Authorization Application (MAA)

A Marketing Authorization Application (MAA) is an application submitted to the European Medicines Agency (EMA) to market a medicinal product in the EU member states.

Neutralizing Antibodies (NABs)

NAB is an antibody that defends a cell from a pathogen or infectious particle by neutralizing any effect it has biologically.

Pivotal trial

A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase 2 studies can be used as pivotal studies if the drug is intended to treat life threatening or severely debilitating conditions.

Panel Reactive Antibody (PRA)

PRA is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0% and 99%. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development

Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Randomized Control Trial (RCT)

RCT is a study design where the trial subject is randomly allocated to one of two or more study cohorts to test a specific intervention against other alternatives, such as placebo or standard of care.

Streptococcus pyogenes

A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

Standard of Care (SOC)

Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.